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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,829

01/13/2006

David W. Old

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EXAMINER

GALLIS, DAVID E

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

03/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,829	Applicant(s) OLD ET AL.	
	Examiner DAVID E. GALLIS	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 4, 7, 8, and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 3, 7, 8, and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 3, 4, 7, 8, and 9 are pending. Claims 1, 2, 5, 6, and 10 have been cancelled. Claims 3, 7, and 9 have been amended. Amendment, 37 CFR 1.132 affidavit, and response filed December 10, 2007 have been entered and carefully considered.
2. With respect to the prior rejection of claims 1 through 5 and 7 through 9 on the ground of anticipation by Elworthy under 35 USC 102(e), Applicants have cancelled claims 1 and 2, and have amended claim 3 to include only the species containing an unsubstituted phenyl moiety. Therefore the rejection of pending claims 3, 4, 7, 8, and 9 as anticipated by the cited art is hereby withdrawn.
3. With respect to the prior rejection of claim 9 on the ground of nonenablement under 35 USC 112 first paragraph based on an incorrect experimentation subject in the Rule 1.132 affidavit, Applicants' expert has corrected the experimental topic to properly reflect EP4 receptors. Therefore the rejection of pending claim 9 as not enabling with respect to EP4 receptor data is hereby withdrawn.
4. With respect to the prior rejection of claims 1, 2, 3, 6, 7, and 10 on the ground of nonenablement under 35 USC 112 first paragraph, Applicants have cancelled claims 1 and 2, amended claims 3 and 7 to include the ester derivative of the claimed species rather than a prodrug. Therefore the rejection of pending claims 3 and 7 as not enabling is hereby withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1625

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claim 9 under 35 USC 112 first paragraph as failing to comply with the enablement requirement is maintained for reason of record.

As discussed in the previous office action, the specification, while being enabling for treatment of glaucoma and intraocular hypertension, does not reasonably provide enablement for preventing those conditions. Applicant has provided a reference by Kass et al. that teaches prevention of the onset of primary open angle glaucoma (POAG), however limited to a population consisting of “individuals with elevated IOP (intraocular pressure)”. This prevention of POAG in the cited candidate population does not extrapolate to all individuals. On reconsideration of the suggested remedy for this rejection, it has been determined that enablement has not been established for prevention of glaucoma in all individuals with elevated IOP.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 7 and 8 recites dependencies for claims 1 and 2, both of which have been cancelled. There is insufficient antecedent basis for these references to non-existent base claims.

9. Since this Office Action contains a 35 USC 112 first paragraph rejection based on the reevaluation of previously suggested remedy **THIS ACTION IS NON-FINAL.**

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis
Patent Examiner

/ Bernard Dentz/

Primary Examiner, Art Unit 1625